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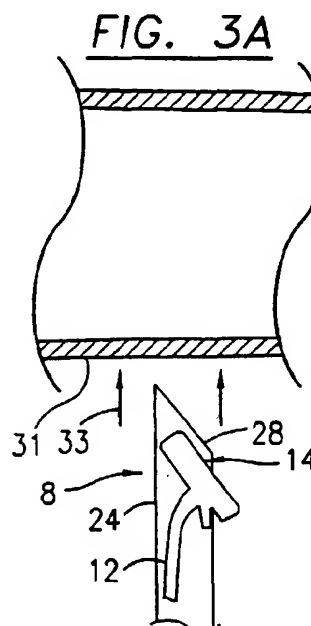
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81369 München (DE)**(54) **Suture with toggle and delivery system**

(57) The self securing suture includes a suture having at least one terminal end and a toggle threat. In one embodiment, the suture toggle is a bar. In another embodiment the suture is a wire and the toggle is a wire element toggle. In a further embodiment, the toggle is angled with respect to the suture filament. The suture delivery system includes a slotted needle configured such that a protruding tab or leg of the toggle bar fits within slot of the needle. For wire sutures, an open loop wire element toggle fits within the slotted needle. In another embodiment, a depending wire tip, from the wire element toggle, fits within the slot and the needle. In a further embodiment, the toggle is angled and the acute angle cavity catches on the lumen of the needle and extends outboard thereof. In use, after the needle pierces the bodily structure blood vessel, tissue or organ, the tab, leg, depending wire tip, open loop wire segment or angulated and protruding toggle head segment coacts with the inboard portion of the bodily structure, blood vessel, tissue or organ, and, as the delivery needle is withdrawn, the toggle at the terminal end of the suture remains in the bodily structure, tissue or organ. The toggle is then fully deployed being generally normally disposed (perpendicular) or angled with respect to the length or axial center line of the suture. When the suture has two suture toggles, one at each terminal end of a suture thread or suture wire body, the physician can easily deploy the suture toggles on either side of an arterial puncture site (for example), tie off the suture thread or suture wire body and thereby close the

puncture.



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## Description

## Technical Field

5 **[0001]** The present invention relates to a biomedical device, namely, a self securing suture with a toggle at its end and associated delivery systems.

## Background

10 **[0002]** In order to pass a suture through a tubular organ or other structure in a body (a human body or an animal), it is necessary to traverse the bodily structure, tissue or organ completely and encircle the area where the physician or medical technician wishes to place the suture. This traverse and encircle method works well in situations where easy access is available to the structure, tissue or organ and the item to be sutured is easily viewed by the physician. In limited access situations (for example, in laposcopic surgery, cardiac surgery and vascular surgery), the traverse and encirclement by sutures is often times difficult, dangerous and at other times impossible.

15 **[0003]** As a further example, an attempt to suture a blood vessel through a small puncture wound is almost impossible. The direct suture of the arterial puncture is not possible.

**[0004]** The increasing utilization of minimally invasive surgical techniques has created a need for improved methods, suture systems and suture placement devices under adverse conditions of limited access and limited visibility of the suture site.

20 **[0005]** U.S. Patent No. 4,669,473 to Richards et al. discloses a surgical fastener having a T-shaped head on a terminal end of a filament. To deliver the surgical fastener into tissue, the head is twisted relative to the filament and the head is pushed through a delivery tube to the surgical site. U.S. Patent No. 4,705,040 to Mueller et al. disclose a T-shaped bar, having a length of 0.25 inches, at the end of a suture. The bar is held in place by a melted ball of material

25 at the terminal end of the suture.

## Summary

**[0006]** It is an object of the present invention to provide a suture which can be self secured on a bodily structure, blood vessel, tissue or organ with a toggle at the terminal end of the suture.

30 **[0007]** It is another object of the present invention to provide a generally T-shaped toggle which latches on an interior or inboard surface of a bodily structure, tissue and organ thereby permitting the balance of the suture to be drawn in and wherein the toggle grasps the bodily structure, blood vessel, tissue and organ.

**[0008]** It is a further object of the present invention to provide a toggle configured as a bar at the end of a suture.

35 **[0009]** It is another object of the present invention to provide a metal wire suture with a T-shaped toggle or a toggle wire element attached to the terminal end of a suture wire.

**[0010]** It is a further object of the present invention to provide a suture and a suture toggle wherein the suture toggle includes a protruding leg or tab which is utilized by a needle delivery system to insert the suture toggle into the bodily structure, tissue or organ.

40 **[0011]** It is a further object of the present invention to provide a suture delivery system including a slotted needle, within which is seated the leg or tab of the suture toggle, which assists in the process of inserting the suture toggle into the bodily structure, tissue or organ.

**[0012]** It is another object of the present invention to provide a self securing suture with a suture toggle which can be used for minimally invasive surgical techniques.

45 **[0013]** It is a further object of the present invention to provide a suture delivery system and toggle sutures utilized in laposcopic procedures.

**[0014]** The self securing suture includes a suture having at least one terminal end and a toggle thereat. In one embodiment, the suture toggle is a bar. In another embodiment the suture is a wire and the toggle is a wire element toggle. In a further embodiment, the toggle is angled with respect to the suture filament. The suture delivery system includes a slotted needle configured such that a protruding tab or leg of the toggle bar fits within slot of the needle. For wire sutures, an open loop wire element toggle fits within the slotted needle. In another embodiment, a depending wire tip, from the wire element toggle, fits within the slot in the needle. In a further embodiment, the toggle is angled and the acute angle cavity catches on the lumen of the needle and extends outboard thereof. In use, after the needle pierces the bodily structure, blood vessel, tissue or organ, the tab, leg, depending wire tip, open loop wire segment or angulated and protruding toggle head segment coacts with the inboard portion of the bodily structure, blood vessel, tissue or organ, and, as the delivery needle is withdrawn, the toggle at the terminal end of the suture remains in the bodily structure, tissue or organ. The toggle is then fully deployed being generally normally disposed (perpendicular) or angled with respect to the length or axial center line of the suture. When the suture has two suture toggles, one at each terminal

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end of a suture thread or suture wire body, the physician can easily deploy the suture toggles on either side of an arterial puncture site (for example), tie off the suture thread or suture wire body and thereby close the puncture.

#### Brief Description of the Figures and Drawings

##### [0015]

FIGS. 1A and 1B diagrammatically illustrate a suture with a suture toggle;  
 FIGS. 2A and 2B diagrammatically illustrate a suture delivery needle with and without the suture toggle;  
 FIGS. 3A, 3B, 3C, 3D and 3E diagrammatically illustrate the insertion and deployment of the suture toggle and, more particularly, FIG. 3E generally diagrammatically illustrates the size relationship between the suture toggle and a typical large artery in a human body;  
 FIGS. 4A, 4B and 4C diagrammatically illustrate a suture delivery system needle, a suture toggle and a modified delivery system;  
 FIGS. 5A-5F diagrammatically illustrate various protruding legs, tabs and other elements protruding from the suture toggle which assist in deployment of the suture toggle in the bodily structure;  
 FIGS. 5G and 5H diagrammatically illustrate various suture toggles with depending tabs;  
 FIG. 6 diagrammatically illustrates a suture having two terminal ends and two suture toggles;  
 FIG. 7 diagrammatically illustrates a suture with two suture toggles, at both terminal ends of a suture thread, deployed about an arterial puncture site;  
 FIGS. 8A-8C diagrammatically illustrate other suture toggles;  
 FIGS. 9A-9B diagrammatically illustrate a suture delivery system with and without a suture toggle;  
 FIGS. 10A and 10B diagrammatically illustrate the deployment of the suture toggle illustrated in FIG. 8A;  
 FIGS. 11A, 11B and 11C diagrammatically illustrate other types of tabs protruding from suture toggles;  
 FIG. 12 diagrammatically illustrates a suture toggle deployed in a suture delivery needle;  
 FIGS. 13A and 13B diagrammatically illustrate a suture toggle configured as a cylinder with a protruding side leg;  
 FIG. 13C diagrammatically illustrates a suture toggle configured as an angled T-bar deployed in a needle;  
 FIGS. 14A and 14B diagrammatically illustrate one delivery system for the suture and suture toggle utilized in conjunction with minimally invasive surgery;  
 FIGS. 15A and 15B diagrammatically illustrate front and side views of the suture delivery needle;  
 FIGS. 16A, 16B and 16C diagrammatically illustrate various configurations of the needle retention body or structure;  
 FIG. 16D is a cross-sectional view of the delivery system from the perspective of section line 16D'-16D" in FIG. 14A;  
 FIG. 17 diagrammatically illustrates an arterial puncture site in a large artery in a human;  
 FIG. 18 diagrammatically illustrates another type of suture delivery system;  
 FIG. 19 diagrammatically illustrates an exploded view of the suture delivery system shown in FIG. 18;  
 FIGS. 20A, 20B, 20C and 20D diagrammatically illustrate cross sectional views of the delivery system shown in FIG. 19 from the perspective of the corresponding section lines in FIG. 19;  
 FIGS. 21A-21F diagrammatically illustrate various configurations of wire sutures and wire toggle elements;  
 FIGS. 22A-22D diagrammatically illustrate needle delivery systems for the wire suture toggles;  
 FIGS. 23A-23C diagrammatically illustrate a laproscopic device for the suture toggle delivery system and FIG. 23D is a cross-sectional view of a suture wire capture system (similar capture systems may be used with suture threads on the delivery systems in FIGS. 14A and 18);  
 FIGS. 24A-24C diagrammatically illustrate major operational steps to deploy suture toggles during laproscopic surgery with the delivery system shown in FIG. 23A; and,  
 FIGS. 25A, B, C and D diagrammatically illustrate a hooked wire suture.

#### Detailed Account of Carrying Out the Invention

[0016] The present invention relates to self securing sutures, that is, sutures having toggles at the suture's terminal end, and various suture delivery systems.

[0017] FIGS. 1A, 1B, 2A and 2B diagrammatically illustrate sutures having toggles at the terminal end and a needle delivery system used in conjunction with the suture toggles. FIGS. 14A and 18 diagrammatically illustrate simple delivery systems for the suture toggles. FIGS. 21A, B, C, D, E and F show wire suture toggles and FIG. 23A shows a delivery system for laproscopic surgery or other type of surgery wherein the surgeon seeks to suture fascia.

## General Principles

[0018] By utilizing the toggle principle, it is possible to enter the bodily structure, tissue or organ and fix one end of a suture to the structure or tissue without encircling the area. If two separate toggle sutures are fixated in this fashion, it becomes possible to tie those sutures with ease without the need for blind encirclement of the area in question. The increasing utilization of minimally invasive surgical techniques and arterial puncture site repair has created a need for improved methods of suture placement under adverse conditions of visibility and access.

[0019] The toggle principal lends itself well to the placement and fixation of sutures, ligaments, etc. In this approach, a suture or wire or other flexible attachment or closure device is passed through or into the tissue in a closed state. The "closed state" refers to the suture toggle deployed in the needle. Upon applying tension after the toggle leaves the needle tip, the toggle is positioned so that it cannot retrace the path through which it was applied or inserted by virtue of the fact that its shape and position will no longer allow egress from the bodily structure or tissue. Structures such as sutures or ligaments attached to the toggle are thereby fixed. One general embodiment of this invention consists of a T-shaped attachment to the end of a suture of either the same or different biocompatible material. The T bar is stiffer than the suture line, thread or wire and offers significant resistance to extraction from the bodily structure once deployed. The suture toggle design in fine wire allows the insertion of the toggle, but restricts the egress from the tubular structure. With respect to wire sutures, provision is made for the applying or delivery device to secure both wires together and close the defect by shortening the wire by the simple, but effective, expedient means of twisting the instrument and its contained wires to secure them together. Provision is made to score the wires at the appropriate location so that the wires divide or separate upon twisting with a small, but secure, stub of twisted wire. In the alternative, a twisting and cutting instrument can be slid down the two opposing wires after the applicator is removed and the wires retained. This instrument would permit twisting and subsequent cutting of the wires in a blind procedure.

## Basic Details of Operation

[0020] The applying device or delivery system consists of a small hollow core needle which allows it to be passed over a guide wire which has been retained at the puncture site. The delivery system contains two small hollow needles in opposition at just the right distance on either side of the guide wire and, thus, the puncture site. In another iteration, the needle can be solid with hollow small toggle suture ends fitted over the needle rather than through them. In the first design, the needles are designed to contain the toggles and the wire or sutures. When the instrument is slid over the guide wire and through the skin incision site of puncture it is advanced until it is against the vessel or structure sought to be closed by a suture. In the case of a vein or artery, a "flashback" tube can be utilized in advance of the needles to demonstrate that the instrument is in the proper position. In addition, the length and design of the "flashback tube" is such that it protects the far wall of the structure, preventing toggling of two walls simultaneously. The restricted length of the hollow needles also protects opposite walls of the artery or vein. A slide moves the two needles distally and then advances the needles through the vessel or structure wall until the toggles are deposited in the blood vessel with their trailing suture or wire leading from the vessel. The hollow needle also acts as a flashback tube bilaterally. The shape of the toggle, as designed, prevents egress from the vessel and traction on the wire or suture "sets" the T of the toggle flush against or in the structure wall. The suture is then tied or the wire twisted as appropriate.

[0021] Different toggle designs are provided as shown in the accompanying drawings. In this fashion, puncture wounds or other defects may be easily closed utilizing simple and inexpensive devices. The cost of complicated closure devices has been a deterrent to the universal acceptance of these previous devices. The utilization of a simple, inexpensive disposable device should remove many of the impediments for universal useage. The concept of toggling sutures for closure is new, safe and simple to use.

[0022] In one of the embodiments presented here, fine, partially annealed wire sutures are utilized to simplify the process by permitting fastening by simple twisting of the wires by the instrument, instead of having to resort to complex methods of tying. Scoring the wires at the appropriate distance allows them to break with twisting at a predetermined location leaving only a small wire stump on top of the structure.

[0023] Any biocompatible material for the suture and suture toggle may be used such as stainless steel wire, nylon sutures, or other synthetic biocompatible material. The methods of tying the sutures may vary with the materials used, but the toggling principle remains the same.

[0024] FIGS. 1A and 1B diagrammatically illustrate a suture 10 having a suture thread or suture body 12, a terminal end 13 and a toggle 14. FIG. 1B shows a side view of suture toggle system 10. In the illustrated embodiment, toggle 14 is generally a solid rectangular shape having a length 1, a width w (FIG. 1B) and a depth d. The width w of the toggle 14 is substantially similar to the outside diameter of the suture thread 12 as shown in FIG. 1B. Toggle 14 has chamfered ends and edges, one of which is chamfer edge 15. This chamfer reduces sharp edges. Further, toggle 14 includes an extending leg 16 protruding outboard away from terminal end 13 of suture 12. Extending leg 16 defines, in combination with toggle body element 18, an open catch mouth 20 leading to a narrower throat 21. Mouth 20 has a gap size large

enough to be captured by a slot in the delivery needle discussed later. Leg 16 protrudes in a direction opposite the attachment of suture 12 to toggle 14.

**[0025]** FIGS. 2A and 2B diagrammatically show a suture delivery system 8 which includes needle 24 having a lumen 26, a piercing terminal end 28 and an open ended slot 30. Open ended slot 30, sometimes called a needle toggle slot herein, is open at the piercing end segment 28 of needle 24. In the illustrated embodiment, piercing terminal end segment 28 (typically a sharp edge) of needle 24 is angularly disposed with respect to the axial center line of needle 24.

**[0026]** Toggle suture system 10 is shown as disposed in lumen 26 of needle 24 in FIG. 2B. Suture toggle 14, and particularly protruding leg 16, is adapted to seat within slot 30 of needle 24.

**[0027]** FIGS. 3A-3D diagrammatically illustrate basic operational characteristics of suture toggle system 10. Similar numerals designate similar items throughout all the drawings. In FIG. 3A, suture delivery system 8, consisting of needle 24 loaded with suture 12 and suture toggle 14, approaches a bodily structure, tissue or organ wall 31. As an example throughout the drawings (excepting drawings FIG. 24A-24C), reference will be made to arterial wall 31. However, any type of bodily structure, tissue or organ may be sutured using the suture toggle system 10 discussed herein. Wall 31 is representative of other bodily structures tissues and organs. Delivery system 8 approaches arterial wall 31 as shown by arrow 33. Piercing end 28 of needle 24 ultimately pierces and enters arterial wall 31.

**[0028]** FIG. 3B diagrammatically shows that needle 24 has fully entered and passed through arterial wall 31. At this point in time, blood flow is noted by a "flash" from the lumen 26 of needle 24. Other "flash back" systems may be utilized. See central tube 62 in FIG. 14A. This flash of blood provides a visual indication to the physician that the needle 24 has fully penetrated into the lumen of the artery or other structure.

**[0029]** In FIG. 3C, the physician is withdrawing needle 24 and protruding leg 16 of toggle 14 is caught on the inboard surface of arterial wall 31. In FIG. 3D, needle 24 is withdrawn from arterial wall 31 and toggle 14 and suture 12 is self secured in artery wall 31.

**[0030]** FIG. 3E diagrammatically illustrates the general proportional size relationship between artery wall 31, the artery in general, toggle 14 and suture 12. To further illustrate one proposed embodiment of the suture toggle, the following Exemplary Dimensional Table is provided.

Exemplary Dimensional Table	
head length	0.10-0.12mm
head depth	0.020mm
OD suture	3/0 nylon
suture length	18 inches
head width	0.10-0.012mm
gap	0.008mm or more
typical delivery needle	0.028mm OD
	0.023mm ID
	21 gauge
large artery size	about 7mm ID

**[0031]** FIG. 4A diagrammatically illustrates suture toggle 14 and suture thread 12 disposed in needle 24. Protruding leg 16 is also disposed in slot 30. However, suture thread 12A is disposed outside of needle lumen 26. This is accomplished by providing a secondary slot 34 within which passes suture thread A. Secondary slot 34 is sometimes referred to herein as a suture slot in the needle.

**[0032]** FIG. 4B diagrammatically shows open ended suture slot 34 at terminal end 29 of needle 24. Terminal end 29 of needle 24 is part of piercing terminal end 28. In the illustrated embodiment, suture slot 34 is opposite toggle slot 30 which retains, in a loaded mode, protruding leg 16 of suture toggle 14. The position of the suture slot relative to the toggle slot varies dependent upon the position of the protruding leg, tab, wire element or loop on the suture toggle.

**[0033]** FIG. 4C diagrammatically shows needle 24 within which is loaded suture toggle 14. Protruding leg 16 protrudes towards suture thread 12A. In this illustrated embodiment, slot 30 also operates as a suture slot. In addition, needle 24 includes rib 36 which enables the suture needle to be inserted into the blood vessel 31 by a pushing in action.

**[0034]** FIGS. 5A through 5H diagrammatically illustrate various modifications of suture toggle 14. FIG. 5A diagrammatically illustrates suture toggle 14 having a protruding leg 16 which protrudes outboard from the toggle opposite

suture thread 12. Particularly, toggle 14 is a toggle bar. As used herein, the term "toggle" refers to a piece or a device for holding or securing suture thread 12. The term "toggle" also encompasses the concept that it is a cross piece attached to the end of suture thread 12 in order to prevent slipping or removal of the suture. The following Bar Shape Table provides some illustrative examples of the geometric shape of the toggle bar.

Bar Shape Table	
.	a straight piece of suture material which is longer than it is wide
.	rectangular
.	oblong
.	elliptical
.	an elongated cylinder

[0035] As used herein, the term "bar" refers to a straight piece which is longer than it is wide. As shown in FIG. 5A, leg 16 is formed from a partially separated segment of toggle bar 14. Remaining segment 18 continues to form part of the toggle bar basic shape.

[0036] FIG. 5B shows a depending protruding leg 38 which protrudes inboard toward suture thread 12. Leg 38 is cut away or formed from toggle bar segment 39. Leg 38 is retained by and captured within open ended toggle slot 30 of needle 24. Gap 20 between leg 38 and toggle remainder section 39 is one of the important features.

[0037] FIG. 5C diagrammatically illustrates toggle suture 14 including a tab 40 depending from inboard surface 41 of suture toggle 14. Inboard surface 41 is integral with or attached to suture terminal end 13. Surface 41 is inboard with respect to suture thread 12.

[0038] FIG. 5D diagrammatically shows tab 40 depending toward suture thread 12. FIG. 5D shows tab 40 consisting of either a solid triangular body, a finger or a conical body. The width of tab 40 is smaller than suture toggle 14. Protruding tab 40 has a raised terminal edge 42, see FIG. 5E, which faces away from suture thread 12. Tab 40 coacts with open ended slot 30 of suture delivery needle 24 (see for example FIG. 4B). The tab fits in toggle slot 30. In a different embodiment, suture slot may be placed 90 degrees from toggle slot 30 (see FIG. 9C) to provide clearance of the tab from the thread during withdrawal of needle 24.

[0039] FIG. 5F diagrammatically illustrates suture toggle 14 carrying two tabs 40, 43 depending from inboard surface 41 of suture tab 14.

[0040] FIG. 5G diagrammatically shows tab 40 as a solid triangular body. Suture toggle 14 is also a solid rectangular body without chamfered edges.

[0041] FIG. 5H diagrammatically illustrates suture toggle 14 from the perspective of section line 5H'-5H" in FIG. 5G. Tab 40 has a raised terminal edge 42 which faces towards suture thread 14. Accordingly, the tab can either face away from suture thread 12 as in FIG. 5E or towards suture thread 12 as in FIG. 5H.

[0042] FIG. 6 diagrammatically shows suture toggles 14 and 14a disposed at opposite terminal ends of suture thread 12. Suture thread 12 has a length  $l_s$  which is, in one embodiment, about 16-18 inches. FIG. 6 also shows that suture toggle 14 has been deployed beneath body layer 31.

[0043] FIG. 7 diagrammatically shows deployed suture toggles 14 and 14a on blood vessel wall 31. The suture toggles are deployed beneath arterial wall 31. Arterial wall 31 is illustrated as having arterial puncture site 44. Suture toggles tabs 14, 14a are deployed on either side of puncture side 44. Suture thread 12 connects suture toggles 14, 14a. In operation, the surgeon or physician ties off suture thread 12 thereby closing arterial puncture site 44.

[0044] FIGS. 8A, 8B and 8C diagrammatically illustrate suture toggle 14 with a protruding leg 16 along one side. Particularly, FIG. 8A diagrammatically shows suture toggle 14 as a toggle bar with chamfers along its side edges. One of the chamfers is identified as chamfer 15. A protruding leg 16 is formed by partly separating toggle 14 from remaining toggle segment 18. This creates an open mouth 20 which is disposed in the toggle slot in needle 30. See FIG. 2A.

[0045] FIG. 8B shows a top view of suture toggle 14 and clearly shows that protruding and extending leg 16 is formed by partially separating leg 16 from the remaining toggle body portion 18. The generally solid body rectangular toggle bar 14 has sides 2, 3, 4 and 5 which are generally in parallel planes with respect to the axial centerline of suture thread 12 if the thread were laid out straight. Items protruding from toggle bar walls 2, 3, 4, 5 are normal (perpendicular) to the suture thread.

[0046] FIG. 8C shows a toggle end view and toggle mouth 20.

[0047] FIGS. 9A-9D show needle 24 with and without a retained toggle suture. FIG. 9A shows toggle slot 30 in needle 24 located approximately midway along piercing terminal edge 28 of needle 24. The toggle slot can be re-positioned

dependent upon the size of the suture, the leg or tab, and the item to be sutured. FIG. 9B also shows toggle slot 30 of needle 24 approximately midway along needle piercing edge 28. FIG. 9B also shows suture toggle 14 deployed in toggle slot 30. Suture thread 12 runs or passes through the lumen 26 of needle 24.

[0048] In FIG. 9B, slot 30 retains protruding leg 16 which protrudes from side edge 5 of the toggle bar. The side edge protruding leg 16 is shown in FIGS. 8A-8C. Leg 16 protrudes normal or perpendicular to suture thread 12.

[0049] FIG. 9C shows needle 24 having toggle slot 30 and suture thread slot 34. Suture thread slot 34 is formed or created approximately 90 degrees from toggle slot 30.

[0050] FIG. 9D shows suture toggle 14 with a side end protruding leg 16 wherein suture thread 12 runs through suture slot 34 of needle 24.

[0051] FIG. 10A shows suture toggle 14 deployed in arterial wall 31.

[0052] FIG. 10B is a detailed view showing suture toggle 14 deployed on an inboard surface of arterial wall 31. Currently, it is believed that the toggle bar with a leg or tab protruding from bar side 2, 3, 4 and 5 is preferable.

[0053] FIG. 8B shows toggle bar 14 with side surfaces 2, 3, 4 and 5. It is currently believed that a tab or leg protruding from one of the side surfaces is better suited than an outboard extending tab or leg (see FIG. 5A) or a depending tab or leg (see FIG. 5B). The depending leg or the depending tab may injure an arterial 31 in certain situations. When toggle anchoring is required, the depending leg or wire is preferred. An upstanding or outboard tab or leg may impede blood flow. However, in some applications, these tab-leg configurations may be beneficial if it achieves better attachment by the suture toggle on the body structure, tissue or organ. A side leg or tab is currently thought to be better than an outboard leg or tab (see outboard leg 16 in FIG. 1A) because an outboard protruding leg or tab may further complicate and impede blood flow or fluid flow through the bodily structure, tissue or organ, particularly if the structure is an artery or a vein.

[0054] FIG. 11A diagrammatically shows suture toggle 14 having a protruding tab 40 protruding from side surface 5 of the toggle bar.

[0055] FIG. 11B shows protruding legs or arms 50, 51 protruding from side surface 5 of toggle bar 14. A plurality of legs or tabs may be utilized. FIG. 11C shows toggle 14 with a generally planar triangular tab 40 protruding from side face 5. Tab 40 in FIG. 11A is generally conical in structure with squared off surfaces. Tab 40 in FIG. 11C is generally a planar triangle.

[0056] FIG. 12 shows suture toggle 14 with a triangular tab deployed within the lumen of delivery needle 24. Tab 40 of toggle 14 protrudes from toggle slot 30. Suture 12 is deployed such that it exits lumen 26 of needle 24 near proximal edge region 52 of piercing terminal edge 28 of needle 24. Proximal region 52 may be rounded or smoothed to avoid cutting suture thread 12.

[0057] FIG. 13A and 13B diagrammatically illustrate suture toggle 14 configured as a cylindrical bar with a laterally protruding leg 16. Leg 16 is also cylindrically shaped and protrudes laterally from toggle bar element 18. Leg 16 is generally normal to suture thread 12. Leg 16 is not cut from or separated from the cylindrical toggle bar.

[0058] FIG. 13 C diagrammatically illustrates toggle bar 14 at an angle 9 with respect to the axial centerline of suture thread 12. In this configuration, the acute angle 7 between angled toggle bar 14 and suture thread 12 is disposed within suture slot 30 of needle 24. This angulated configuration may enable long T-shaped bar deployment in needle 24. The term "long T-shaped" refers to the length of sides 3,5 (see FIG. 8B) relative to the cross-sectional dimension of suture thread 12. This implementation may also avoid the use of protruding legs, tabs or members.

[0059] FIGS. 14-20 diagrammatically illustrate various suture delivery systems.

[0060] FIG. 14A diagrammatically shows suture delivery system 60 which includes a basic or central tube 62 which runs over a guide wire 64. Guide wire 64 typically is not part of the suture delivery system. The illustrated delivery system in FIG. 14A is used to close puncture wounds made during catheterization. Guide wires 64 are used during such medical procedures. For purposes of explanation, suture delivery needles 66, 68 carry suture toggles and suture threads generally shown and discussed earlier in connection with FIGS 1-13.

[0061] FIG. 15A shows suture needle 66 having a piercing edge 67 and a toggle slot 69. FIG. 15B diagrammatically illustrates a side view of suture needle 66.

[0062] Returning to FIG. 14A, base tube 62 rides over guide wire 64 in order to properly place suture needles 66, 68 on either side of arterial puncture 44 shown in FIG. 7. Suture needles 66, 68 have piercing ends 67, 67a which are laterally deployed a distance 69 from base central tube 62. In this suture delivery system, suture needles 66, 68 are made of metal having a shape memory such that when needle end segment 70 is free from needle containment or retaining structure 72, the distal ends of needles 66, 68 spring laterally outward a distance 69.

[0063] Needles 66, 68 run and protrude through needle retainer body 72 and also protrude proximally from proximal end 74 of retainer 72 towards thumb nut set 76. Proximal needle ends 75, 77 for needles 66, 68 are generally near thumb nut set 78.

[0064] Needle retention structure 72 has a proximal tube member 80 such that tube 80 runs over central tube 62. The operator moves needle retainer structure 72 by moving thumb nut set 78 in the direction shown by arrow 82. As shown in FIG. 16D, proximal tube 80 (attached to needle retainer body 72) has longitudinal slots 73a, 73b. Needles 66,

68 are attached to base or center tube 62. Hence, when tube 62 is stationary and needle retainer 72 is moved, needles 66, 68 are either exposed (FIG. 14A) or fully retained and covered (FIG. 14B).

[0065] FIG. 14B shows that needle retaining structure 72 has been pushed forward such that proximal ends 75, 77 of needles 66, 68 are proximate or near thumb nut set 78. Piercing edges 67, 67a are disposed at, near or below distal edges 79, 81 of needle retention structure 72. When the structure delivery system 60 is placed on guide wire 64 and placed near arterial puncture site 44 (FIG. 17), thumb nut set 78 (mounted on tab 80 and retainer 72) is then withdrawn in a direction opposite arrow 82 in FIG. 14A, and distal end 70 of needles 66, 68 are then exposed and sprung laterally outward due to the memory shape of the needles. The surgeon then places the distal end of tube 62 into arterial puncture 44 (FIG. 17) and continues to move delivery system 60 down guide wire 64 until he or she sees a flash of blood when piercing ends 67, 67a of needles 66, 68 pierce arterial wall 31. A flashback may also occur through base tube 62. Toggle insertion generally occurs at sites 83, 85 (FIG. 17). The surgeon then withdraws the needles thereby leaving the toggle ends of the sutures on the inside arterial wall 31. The surgeon can then close the arterial puncture after removal of guide wire 64 in a manner described above in connection with FIG. 7.

[0066] FIGS. 16A, 16B and 16C show different structures for needle retention structure 72. In FIG. 16A, retention structure 72 is generally circular in configuration. The structure contains left and right passages 82, 84 within which pass needles 66, 68. A central passage 86 permits passage of base tube 62.

[0067] In FIG. 16B, needle retention structure 72 is elliptical or oblong. In FIG. 16C, needle retention structure 72 includes a central cylindrical body 88 and two side bodies 90, 92. Side body 90 has a lumen through which passes needle 66. Side body 92 includes a lumen through which passes needle 68. Central body 88 includes a lumen through which passes central or base tube 62.

[0068] FIG. 17 shows that a typical size of the large artery having dimension  $d_a$  which is approximately 7mm (inside diameter) and puncture site 44 has an approximate opening size  $a_p$  of approximately 2-3mm. The lateral distance between respective piercing edges 37, 37a of needles 66, 68 is approximately 5-6mm. The lumen of the suture toggle delivery needles 66, 68 is approximately 0.02mm. Accordingly, the puncture for the suture toggles is small compared with the size of the arterial puncture which in turn is smaller than the inside diameter  $d_a$  of large artery 31.

[0069] FIG. 18 diagrammatically shows delivery system 60 including a shaped element 94 which forces needles 66, 68 to move laterally in the direction of arrows 96a and 96b outboard and away from central tube 62. Shape element 94 acts as a cam surface and needles 66, 68 follow the proximal cam surface of the shape 94. The proximal end segments of needles 66, 68 are attached to outer tube 80 which is further attached to screw set 78. When outer tube 80 moves forward and aft over central tube 62, the distal ends of needles 66, 68 move forward and aft over cam shape surface 94. Cam shape element 94 is mounted on central base tube 62. The following Needle Delivery Flare Table describes some shapes of the cam shape 94.

Needle Delivery Flare Table

ball
olive
oblong
frustoconical
angled ribs (with apex at a proximal end)

[0070] FIG. 19 diagrammatically shows an exploded view of delivery system 60. Thumb screw set 78 is attached to the proximal end of needle carrying tube 80. Needles 66, 68 are attached to carrying tube 80.

[0071] FIG. 20A shows needles 66, 68 from the perspective of section line 20A'-20A" in FIG. 19. The attachment of needles 66, 68 to needle carrying tube 80 is shown in a cross-sectional view in FIG. 20B from the perspective of section line 20B'-20B" in FIG. 19. The lumen 80a of needle carrying tube 80 is large enough to accommodate central tube 62. Central tube 62 extends through needle carrier tube 80.

[0072] Needles 66, 68 and needle carrying tube 80 are placed over central or base tube 62. Guide wire 64 extends through lumen 63 of central tube 62 when the system is deployed and in use.

[0073] FIG. 20C shows a cross-sectional view of central tube 62 from the perspective of section line 20C'-20C" in FIG. 19. Needle retention body 72 is mounted on central tube 62.

[0074] Needle retention body or structure 72 is mounted on central tube 62. A cross-sectional view of one embodiment of needle retention body 72 is shown in FIG. 20D. FIG. 20 D is a view from section lines 20D'-20D" in FIG. 19. Needle cam shape 94 is attached to the distal end of central tube 62 slightly beyond needle exit ports 98, 99 of needle



retention body 72. It should be noted that needle retention body 72 may take one or more of the shapes illustrated above in connection with FIGS. 16A, 16B and 16C.

**[0075]** To construct the delivery system shown in FIG. 19, needle carrying tube 80 and needles 66, 68 are placed over central tube 62. Needles 66, 68 are fed into needle entrance ports 97a, 97b. Needles 66, 68 are placed into the left and right side needle lumens of needle retention structure 72 until they are proximate needle exit ports 98, 99. Thereafter, thumb nut set 76 is placed on the proximal end of central tube 62 by an appropriate attachment means (e.g., a thread). Accordingly, face 101 of set 76, along section lines 102'-102," is near or adjacent face 103 of set 78 at section lines 104'-104" which is the proximal end of thumb nut set 78. In a preferred embodiment, thumb nut set 78 may cooperate with thumb nut set 76 to lock the needle delivery system and suture delivery system together prior to deploying the system on guide wire 64. After deployment, the system takes the configuration shown above in connection with FIG. 14B except central tube 62 includes a needle cam shape 94. This cam shape is absent from FIG. 14B.

**[0076]** At the time of suture toggle deployment, needle carrying tube 80 is moved distally while central tube 62 remains stationary thereby causing needles 66, 68 to leave exit ports 98, 99 and move over needle cam surface shape 94. At that time, the distal ends of needles 66, 68 move laterally outboard (relative to the axial center line) in the direction shown by arrows 96a, 96b in FIG. 18 until the piercing surfaces of needles 66, 68 are distally beyond the needle cam shape 94. At that time, the operator inserts the distal end of central tube 62 into arterial puncture 44 shown in FIG. 17. Thereafter, needles 66, 68 pierce arterial wall 31, deposit the toggles in the artery's lumen and at the underside of arterial wall 31 and the operator withdraws the needles by moving thumb nut set 68 proximally with respect to central tube 62 which is preferably held stationary. This causes needles 66, 68 to withdraw and laterally collapse since cam surface shape 94 no longer forces the distal end of the needles to protrude laterally outward beyond central tube 62. The needles are also drawn into needle retention body 72. When the needles' terminal ends are at or near exit ports 98, 99, the entire delivery system is withdrawn and the surgeon or physician ties off the suture wire as shown in FIG. 7.

**[0077]** FIGS. 21-22 diagrammatically illustrate a toggle suture made of wire. This wire may be stainless steel wire. The toggle may also be memory shape metal. In contrast, the sutures discussed above in connection with FIGS. 1-13 are made of nylon or other synthetic biocompatible material.

**[0078]** FIG. 21 A shows suture wire 110 having a wire element toggle 114 at suture terminal end 113. The wire is typically stainless steel but may be an other type of biocompatible metal material. Wire element toggle 114 includes a double strand segment 116. Wire element toggle 114 is angularly disposed, that is, disposed over angle 118a with respect to the axial central line of suture wire 110. In addition, wire element toggle 114 includes a depending wire tip section 118.

**[0079]** FIG. 21B shows wire element toggle 114 disposed on an inboard side of body structure, tissue or organ layer 31. Depending wire element 118 protrudes into body layer 31 thereby locking or anchoring the toggle suture in place.

**[0080]** FIG. 21C shows wire suture 110 with a wire element toggle 114 being normal with respect to the suture wire. The angular disposition of toggle 114 to the axial centerline of laid-out suture wire 110 is related to the needle delivery system and the spring action and toggle or latch action of the suture toggle.

**[0081]** FIG. 21D shows that depending leg 118 is angularly disposed at angle 121 with respect to the central axis of wire element toggle 114. The angular position is related to the needle delivery system and the degree of locking necessary on bodily structure 31.

**[0082]** FIG. 21E shows suture wire 110 having a wire body 122 (about 16"-18") and having toggle elements 114a, 114b attached to suture terminal ends 113a, 113b.

**[0083]** FIG. 21F shows wire element toggle 114 attached by welding or other type of mounting mechanism to suture terminal end 113.

**[0084]** FIG. 22A shows needle delivery system 124 which retains wire element toggle 114 and wire suture 112. Toggle element 114 includes an open loop 135 and a linear segment 136. Linear segment 136 rests against the proximal end wall of a needle slot 130. Open loop toggles are shown in FIGS. 21E, 22A, C and D.

**[0085]** FIG. 22B shows needle 124 having a toggle needle slot 130 and wire element toggle 114 having a depending leg 118 resting on toggle needle slot 130. Suture wire 110 is disposed in lumen 126 of needle 124. Leg 118 is used to mount suture wire 110 in the delivery needle. Legs 119 are shown in FIGS. 21A, 21B, 21D and 21F.

**[0086]** FIG. 22C shows toggle element 114 with open loop 135 disposed in toggle needle slot 130.

**[0087]** FIG. 22D shows wire element toggle 114 in toggle slot 130 of needle 124. Needle 124 also includes a suture slot 134 through which runs wire suture 110. Wire element toggle 114 is retained within toggle slot 130 via its open loop. The operation of the wire suture and wire element toggle is substantially similar to the suture toggle discussed above in connection with FIGS. 1-13. The operation and deployment of the suture toggle and the suture needle is also similar to that discussed above in connection with FIGS. 1-13.

**[0088]** FIGS. 23A, 23B and 23C diagrammatically show a delivery system 210 used in connection with fascia 220 to deploy suture toggles in a manner discussed above in connection with FIGS. 1-13 and 21-22. The deployment device shown and described in connection with FIGS. 23-24 is typically used in laproscopic surgery. However, it may be used whenever a surgeon needs to suture fascia.

[0089] Delivery system 210 includes handle 222 and central tube 224 which carries thread 226 at its distal end. Thread 226 coacts with threads on an inboard surface of collar 228. Collar 228 is attached to suture needles 230, 232. Suture needles 230, 232 move within needle passages in needle retention body 234. This mechanical theory and feature is generally discussed above in connection with needle retention body 72 and FIGS. 14A and 18.

5 [0090] Central body or tube 224 has a mid-section 224a and a distal section 224b. At the distal end of distal section 224b, a radially large fascia lift element 240 is mounted. A plunge cone 242 is mounted to the distal end of enlarged lift segment 240. Fascia is lifted by the proximal, peripheral radial lip 240a of lift element 240.

[0091] FIG. 23B diagrammatically shows an operational state of delivery system 210. The distal ends 230a, 232a of needles 230, 232 protrude axially beyond the distal end of needle retainer 234. In operation, the suture toggles are deposited in the fascia by rotational movement of body 224 to collar 228 translated into axial movement and needle ends 230a, 232a are withdrawn by counter rotation of central tube 224 thereby moving collar 228 in a proximal direction. Withdraw of the suture needles causes the suture toggles to remain embedded in the fascia.

10 [0092] FIG. 23C shows a delivery system 210 with suture wires 110a, 110b disposed outboard of suture needle ends 230a, 232a. The suture wires are run through capture channels 250, 252 on either side of needle retention body 234.

15 [0093] FIG. 23D is a diagrammatic cross-sectional view from the perspective of section lines 23D'-23D" in FIG. 23C. Suture capture body 252 captures suture wire 110b in a channel 254. Upon deployment of the toggle suture in the fascia, the physician simply moves the suture wire outboard of the channel 254 and closes the site.

[0094] FIGS. 24A, 24B and 24C diagrammatically illustrate the operation of delivery system 210. In FIG. 24A, cone 242 and fascia support or lift element 240 have been inserted into a hole or cavity formed in fascia 220. The surgeon or physician allows the fascia to rest thereby closing the hole about distal central rod segment 224b.

20 [0095] In FIG. 24B, the physician gently raises delivery system 210 in the direction shown by arrow 275. Lift element lip 240a causes fascia 220 to rise thereby lifting fascia 220 above underlying tissue elements 220a. Further, the physician rotates central handle 224 with respect to collar 228 thereby causing suture needles 230a, 232a to protrude beyond the distal end of needle retention body 234.

25 [0096] In FIG. 24C, the physician has completely rotated handle 224 thereby completely deploying needle ends 230a, 232a through fascia 220. Upon complete deployment of the toggle carrying sutures, the suture toggles engage the inboard edge or side of fascia 220 preferably in the interstitial space between underlying material 220a. The toggles are caught by the fascia, leave the toggle carrying needles, latch onto the inboard surface of fascia 220 and remain in the fascia. The surgeon then counter rotates handle 224 with respect to collar 228 thereby withdrawing suture needle ends 230a, 232a from fascia 220. Essentially, needles 230, 232 are withdrawn and recaptured by needle retention body 234. The surgeon then gently withdraws fascia lift element 240 from fascia 220. The toggles are embedded in the inboard surface of the fascia and the surgeon can then close the fascia.

30 [0097] FIGS. 25 A, B, C and D diagrammatically illustrate a wire toggle with a wire suture 310 and a wire toggle element 312. Toggle element 312 is configured as a hook with a crook or bend element 316 (0.008 or greater), an angled body segment 314 and an end segment 318. End segment 318 is generally in a plane parallel with respect to the axial centerline of wire suture 310 assuming the suture is laid out straight. The length of hook end 318 is approximately 0.04. This configuration locks onto the inboard surface of the bodily structure after the wire suture is deployed beneath the surface. See generally FIG. 25D.

40 [0098] FIG. 25B illustrates toggle wire element 312 with a stepped radius or curve consisting of proximal angled segment 320, normal segment 322 (having a running length wr of about 0.020) and angled segment 323. Hook span g from suture 310 to end segment 318 is about 0.60. FIG. 25C shows hooked toggle 312 deployed in a delivery needle 324. In the illustrated embodiment, the needle does not have a suture slot.

45 [0099] FIG. 25D illustrates the deployment of hook toggles 312, 312a and the integral or attached wire sutures 310, 310a twisted or crossed. In the configuration, the wire sutures are enabled to close the illustrated gap in body structure 340.

#### Industrial Application

50 [0100] The present invention has industrial application in the biomedical field.

#### Claims

55 1. A self securing suture (12,110) having a toggle (14,114) at a terminal end (13,113) characterized in that said toggle forms or includes a catch element (16,18,7(FIG.13C),118,135,314) for deployment of said suture.

2. A suture as claimed in claim 1 wherein said suture is a thread of suture material and said toggle is a bar (14) and said catch element is one of a tab (16,40), a plurality of tabs (40,43), a leg (16,18), or an extension.

3. A suture as claimed in claim 2 wherein said toggle has a width substantially similar to an outside diameter of said suture.

4. A suture as claimed in claims 2 or 3 wherein said catch element is formed from a partially separated segment of said toggle bar.

5. A suture as claimed in claims 2 or 3 wherein said catch element is a tab and said tab is one of a solid triangular body (40), a finger (16) and a conical body (40, FIG. 11A) extending from a suture thread inboard toggle bar surface toward said suture thread.

6. A suture as claimed in claims 1, 2, 4 or 5 wherein said suture includes two terminal ends coupled together by a suture thread and the self securing suture includes respective toggle (14, 14a, FIG. 7) at each suture terminal end.

8. A suture as claimed in claim 1 wherein said suture is metal wire (110) and said toggle is a wire element (118, 135, 312) disposed on said suture terminal end (113).

9. A suture as claimed in claims 1 or 8 wherein said catch element is one of a depending wire tip section (118), an open loop wire element toggle (135) and a hook, crook or bend element (312).

10. A suture as claimed in claim 9 wherein said wire suture includes two terminal ends coupled together by a suture wire body and the self securing suture includes a respective wire element toggle at each wire suture terminal end (FIG. 21E).

11. A suture as claimed in claim 1 wherein said toggle is disposed at an acute angle with respect to the suture filament (FIG. 13C, 21A, 25A) and said acute angle forms said catch element.

12. A suture as claimed in claims 1, 2, 6, 8, 9 or 11 wherein the suture filament is made of suture thread material and said toggle is made of different biocompatible material.

13. A suture delivery system enabled to deliver a self securing suture (12, 110) having a toggle (14, 114) at a terminal end (13, 113), and the delivery system having a needle (24) including a lumen (26) and a piercing needle end (28), characterized in that said toggle forms or includes a catch element (16, 18, 7 (FIG. 13C), 118, 135, 314) disposed on said piercing needle end such that a portion of said suture toggle (FIGS. 2B, 4C, 9B, 13C, 22B, 22C, 25C) protrudes from said needle end.

14. A suture delivery system as claimed in claim 13 wherein the suture filament is a thread of suture material and said toggle is a bar (14) and said catch element is one of a tab (16, 40), a plurality of tabs (40, 43), a leg (16, 18), or an extension.

15. A suture delivery system as claimed in claim 13 wherein the suture filament is metal wire (110) and said toggle is a wire element (118, 135, 312) disposed on said suture terminal end (113).

16. A suture delivery system as claimed in claim 13 wherein said toggle is disposed at an acute angle with respect to the suture filament (FIG. 13C, 21A, 25A) and said acute angle forms said catch element.

17. A suture delivery system as claimed in claims 13, 14 or 16 wherein the suture filament is made of suture thread material and said toggle is made of different biocompatible material.

18. A suture delivery system as claimed in claims 13, 14, 15 or 16 wherein said piercing needle end (28) includes an open ended slot (30) which coacts with said catch element (16, 18, 7 (FIG. 13C), 118, 135, 314) for deployment of said suture.

19. A suture delivery system as claimed in claims 13, 14, 15, 16, 17 or 18 wherein said delivery system deploys two self securing sutures with two spaced apart needles (66, 68; 230a, 232a), a respective catch element protruding from a corresponding piercing needle end (67, 67a), and a central tube (62, 224a, b) about which is disposed said needles (66, 68; 230a, 232a) and a needle retainer (72, 234) movably mounted with respect to said needles, said needle retainer capturing each needle end when said needle retainer is at a distal position, and exposing each needle end when said needle retainer is at a proximal position.

20. A suture delivery system as claimed in 19 including a sleeve (80) carrying said needles which sleeve is movably disposed with respect to said needle retainer (72), said delivery system includes a cam (94) distally disposed on said central tube (62) such that when said needle retainer (72) is in said distal position relative to said needles, said needles splay over said cam and when said needle retainer is in said proximal position relative to said needles, said piercing needle ends are captured therein.

21. A suture delivery system as claimed in 19 wherein said needles are mounted onto said central tube (FIG. 16D) and said needles are made of memory shape material such that when said needle retainer is in said proximal position relative to said piercing needle ends, said needles attain their memory shape (FIG. 14A), said needle retainer fixed to an actuator sleeve (80) movably mounted on said central tube.

22. A suture delivery system as claimed in claims 19, 20 or 21 including a bulbous body (240,242) at a terminal end of said central tube.

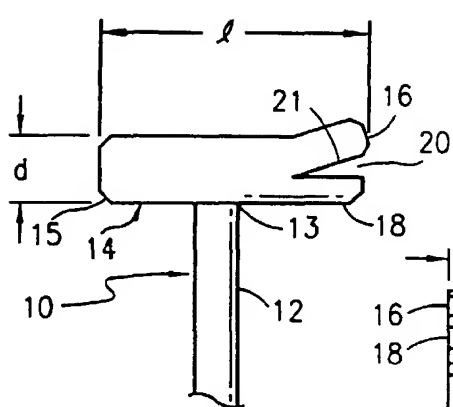


FIG. 1A

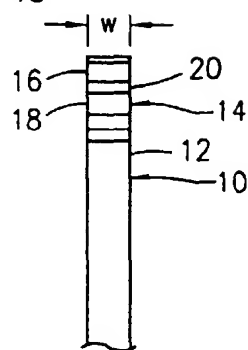


FIG. 1B

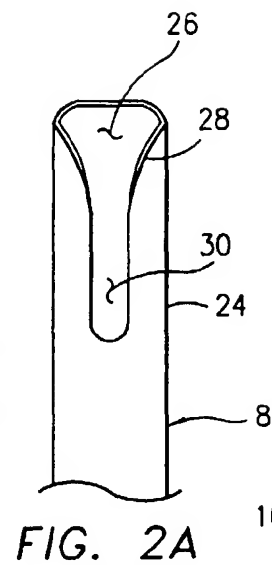


FIG. 2A

FIG. 2B

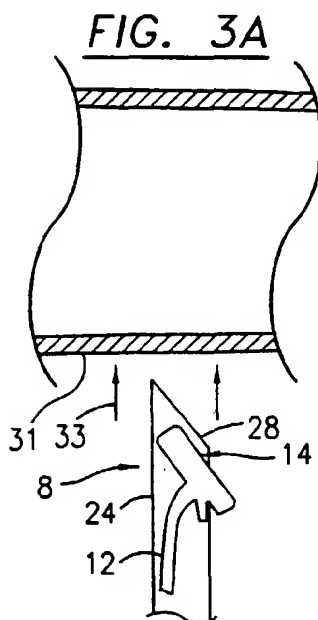
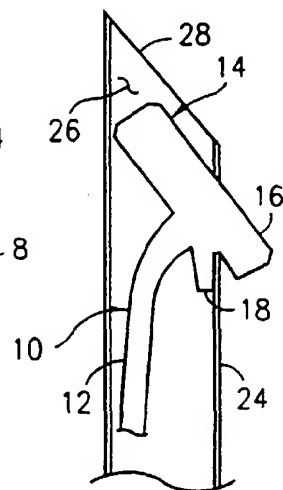


FIG. 3A

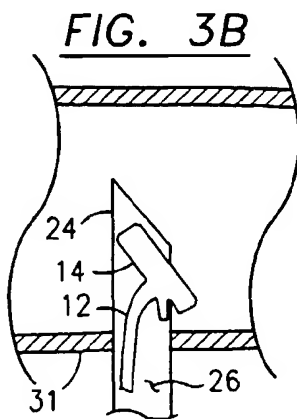


FIG. 3B

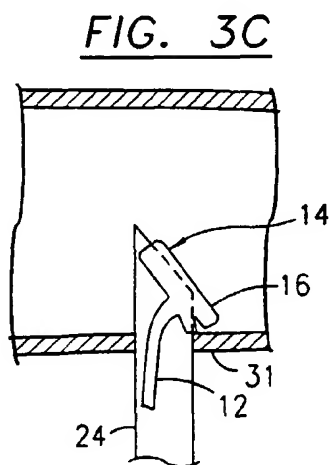


FIG. 3C

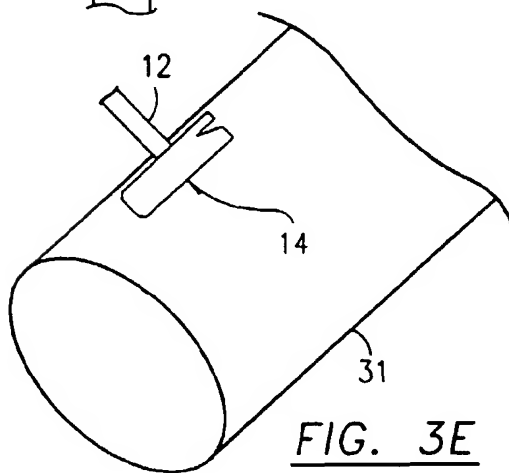


FIG. 3E

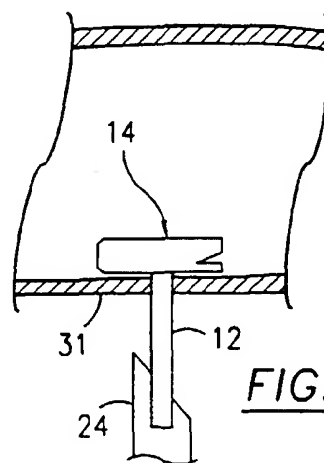


FIG. 3D

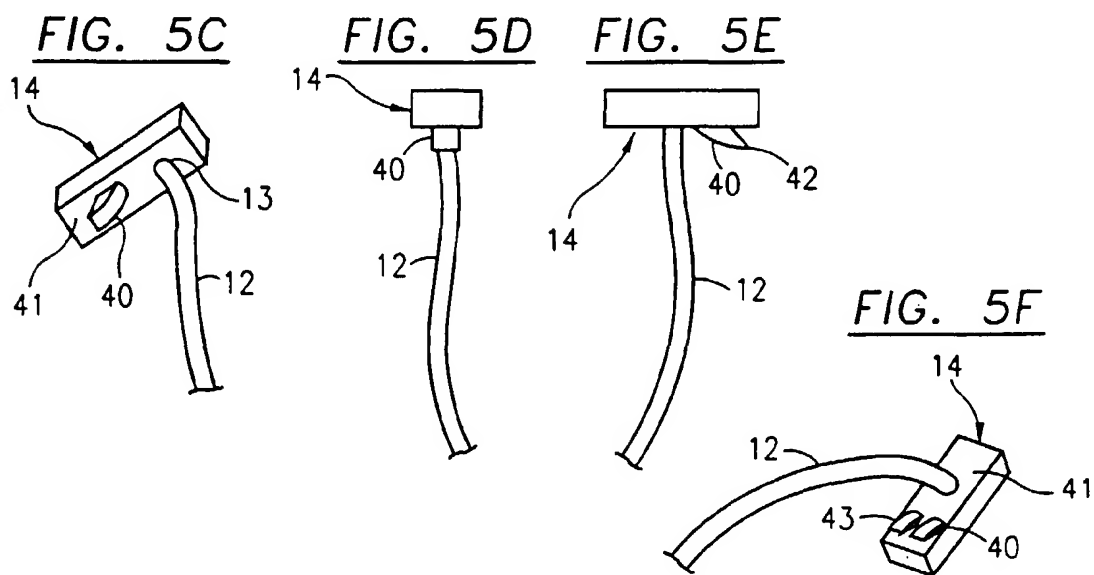
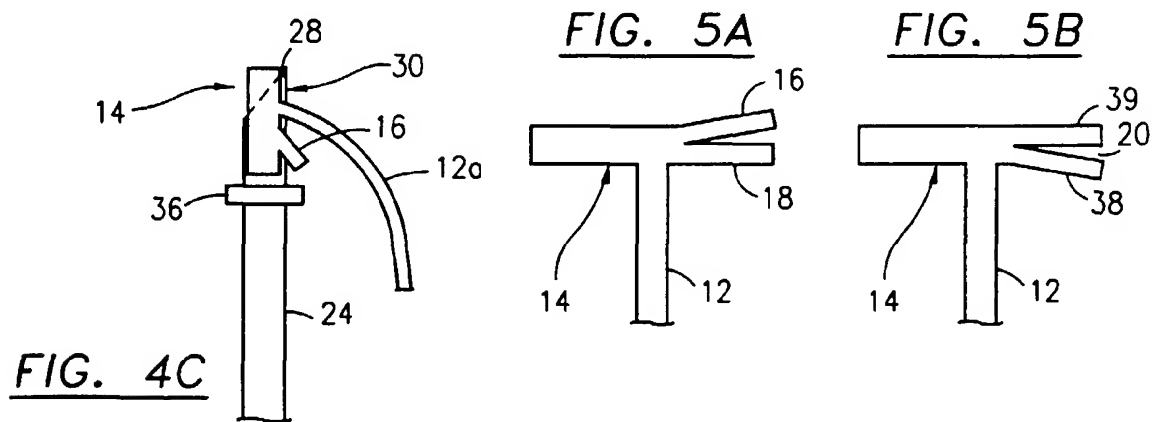
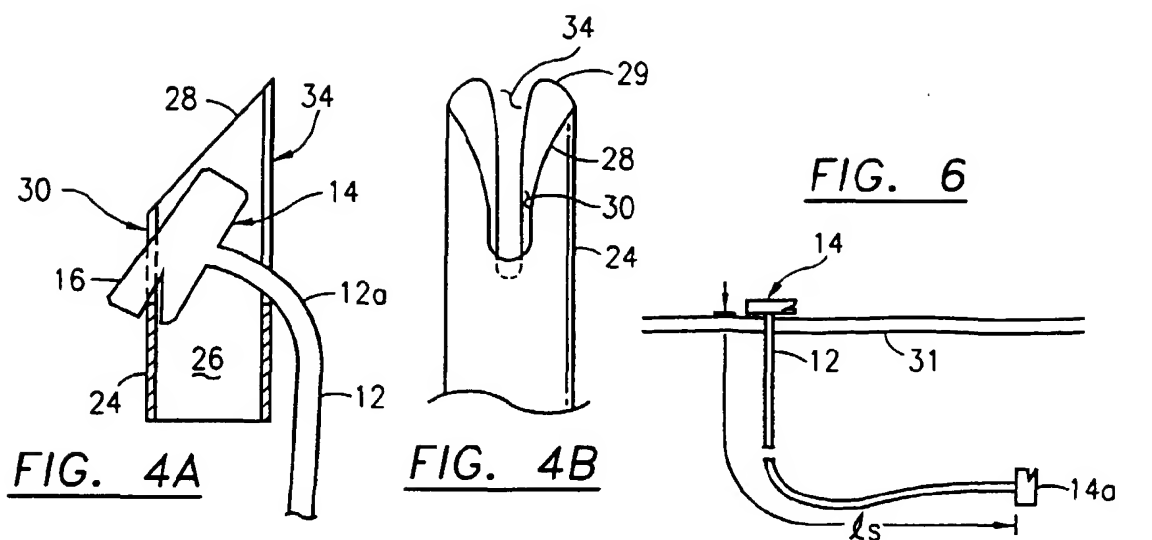


FIG. 5G

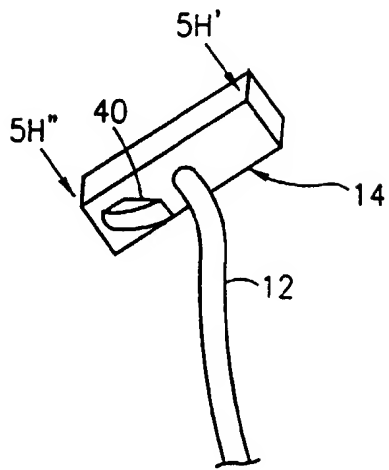


FIG. 5H

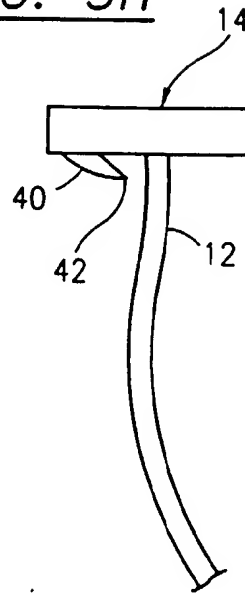


FIG. 7

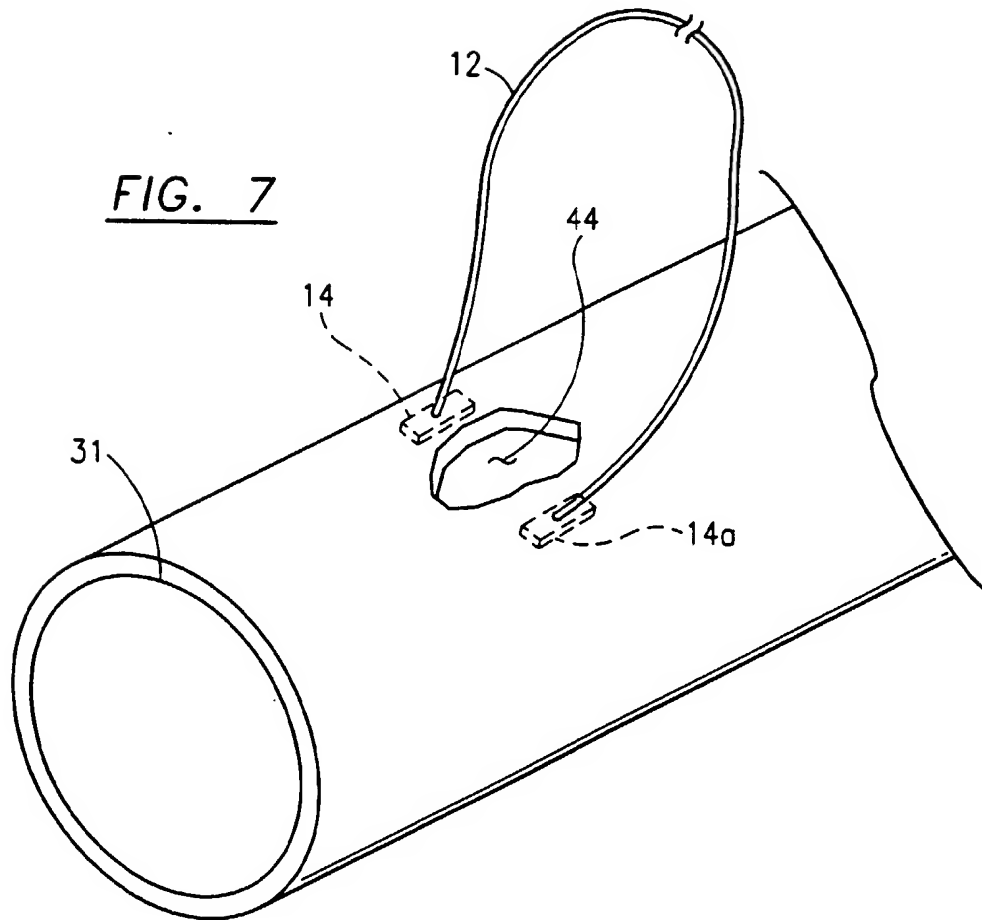


FIG. 8A

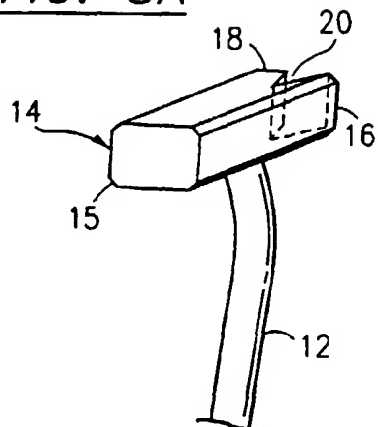


FIG. 8B

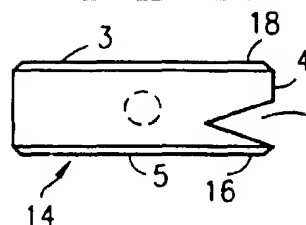


FIG. 8C

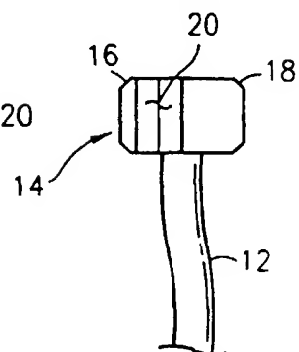


FIG. 9A

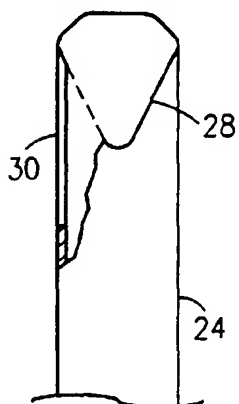


FIG. 9B

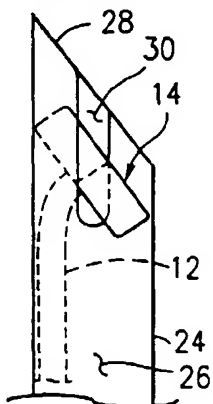


FIG. 9C

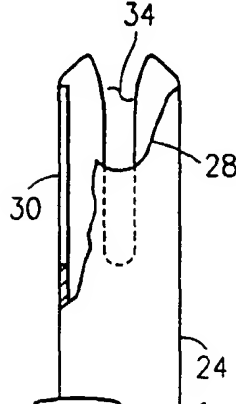


FIG. 9D

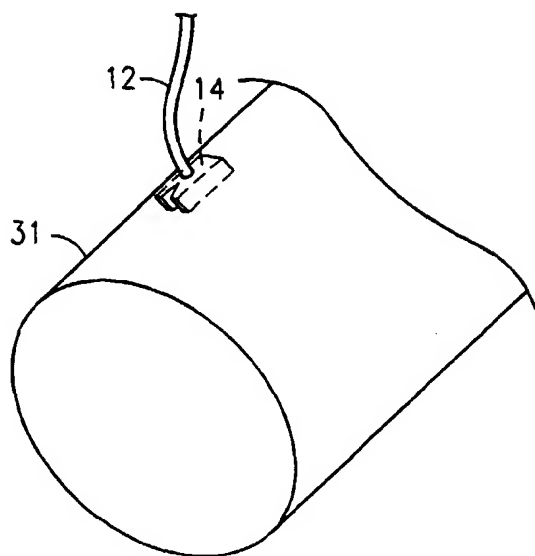
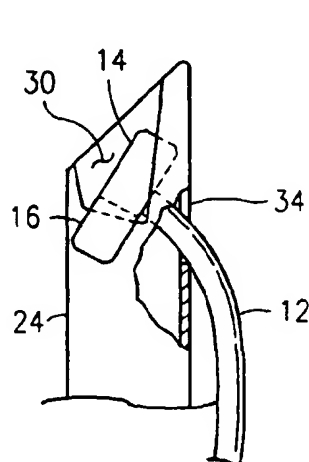


FIG. 10A

FIG. 10B

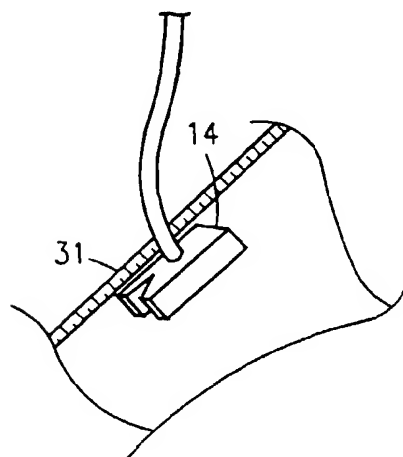




FIG. 11A

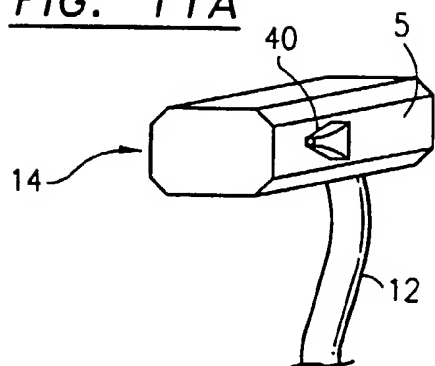


FIG. 11B

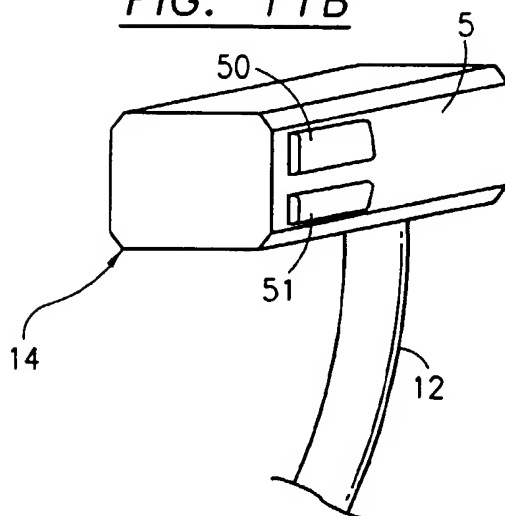


FIG. 11C

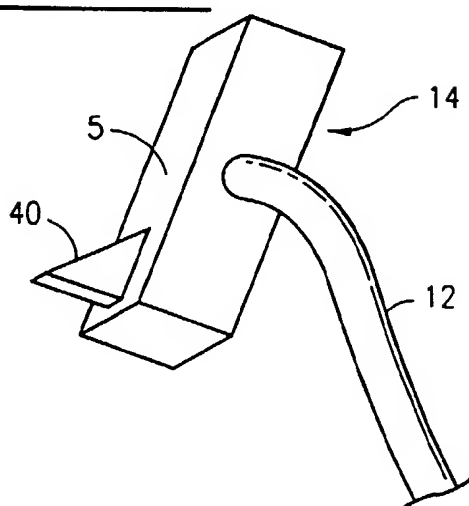


FIG. 12

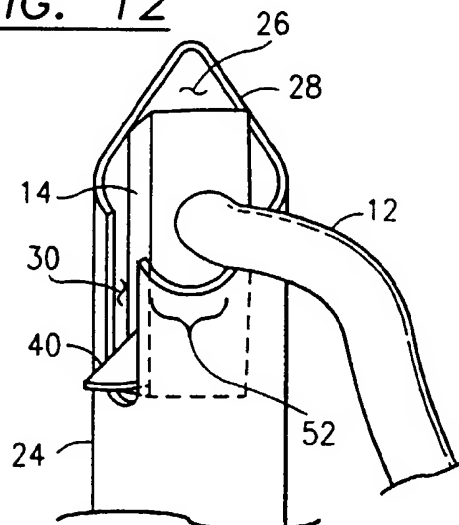


FIG. 13A

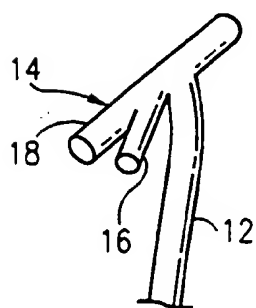


FIG. 13B

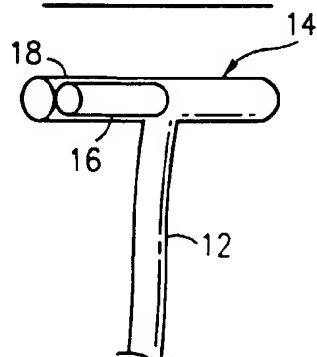


FIG. 13C

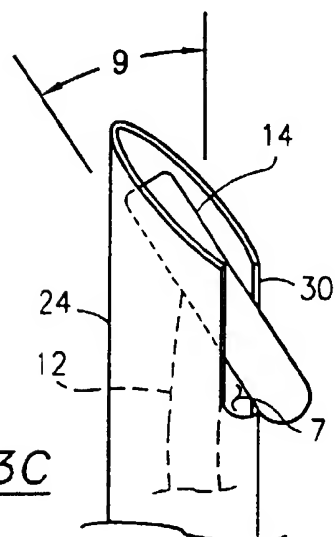


FIG. 14A

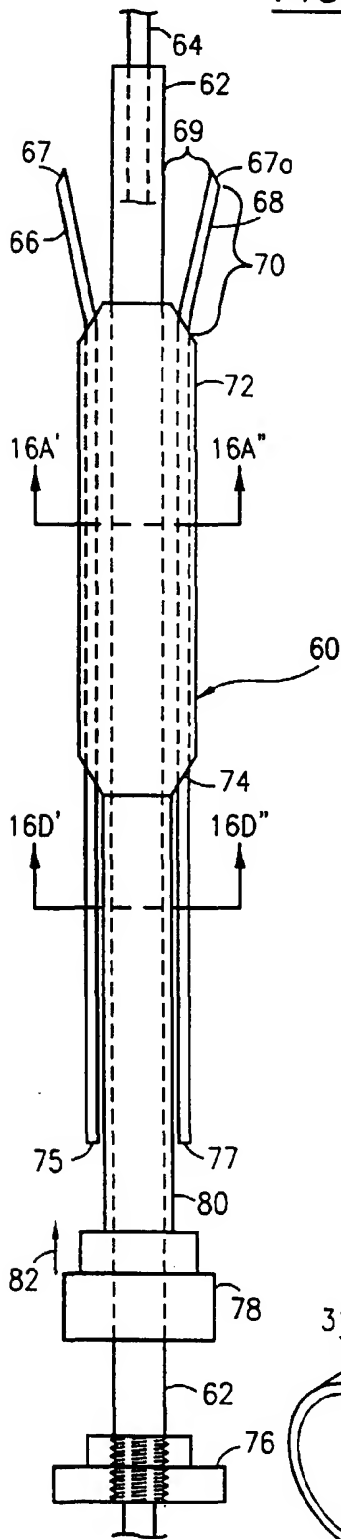


FIG. 15A

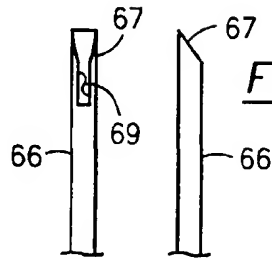


FIG. 16A

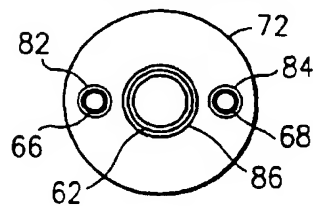


FIG. 16B

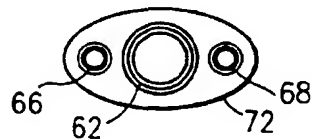


FIG. 16C

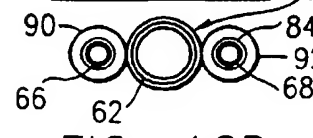


FIG. 16D

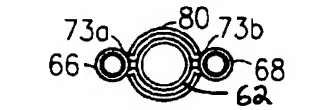


FIG. 17

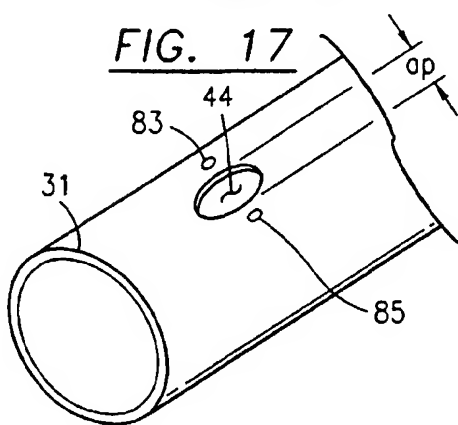


FIG. 14B

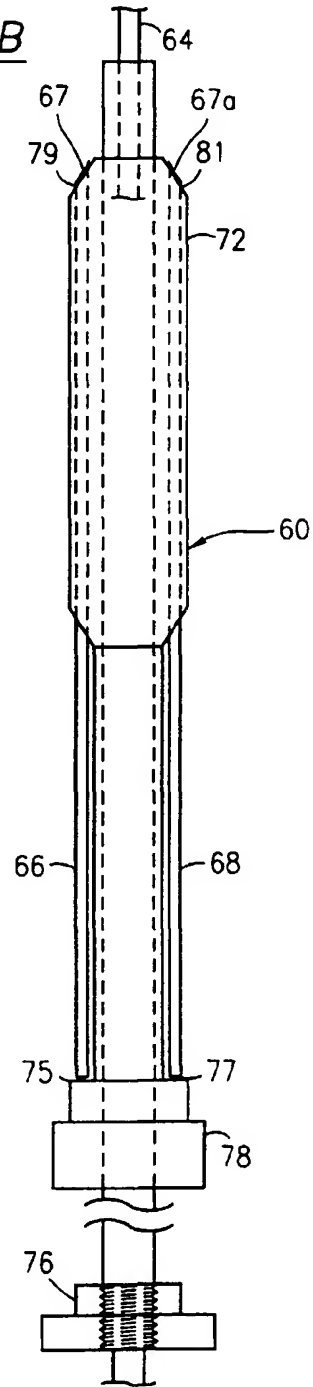


FIG. 15B

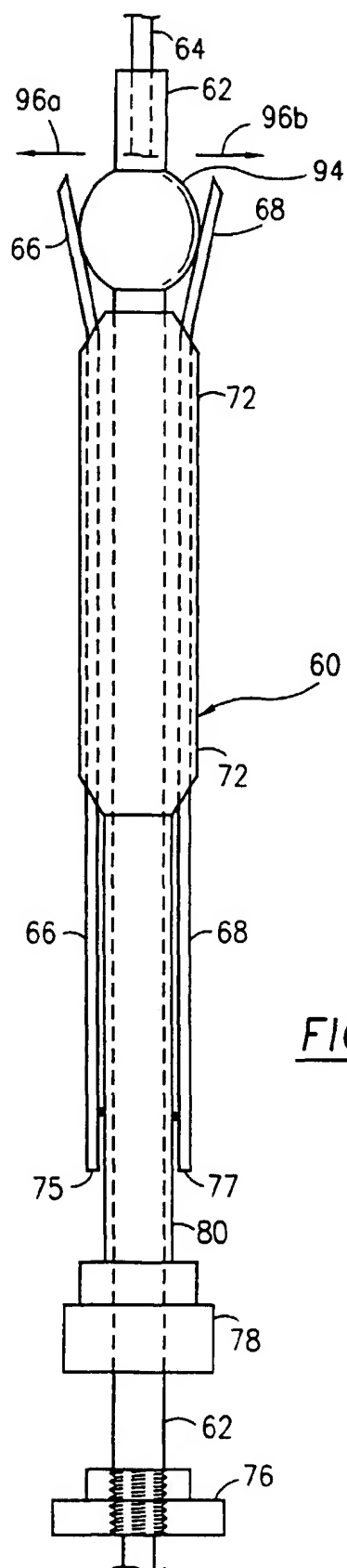


FIG. 19

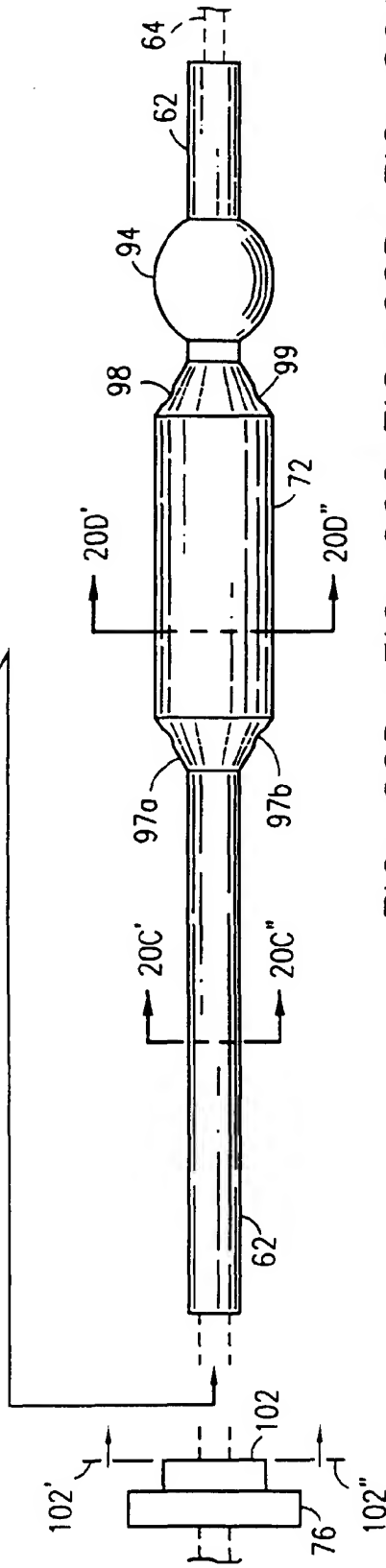
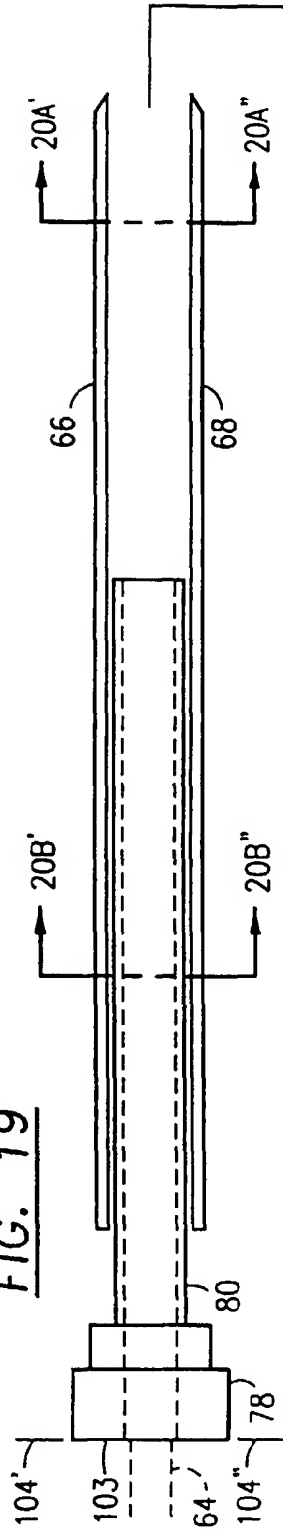
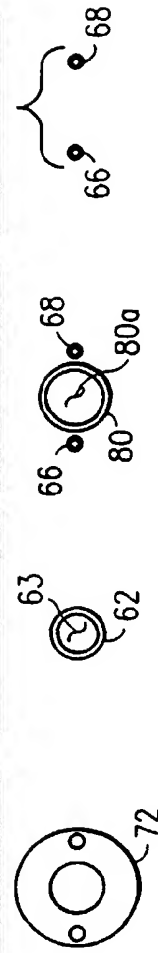


FIG. 20B FIG. 20C FIG. 20D FIG. 20A



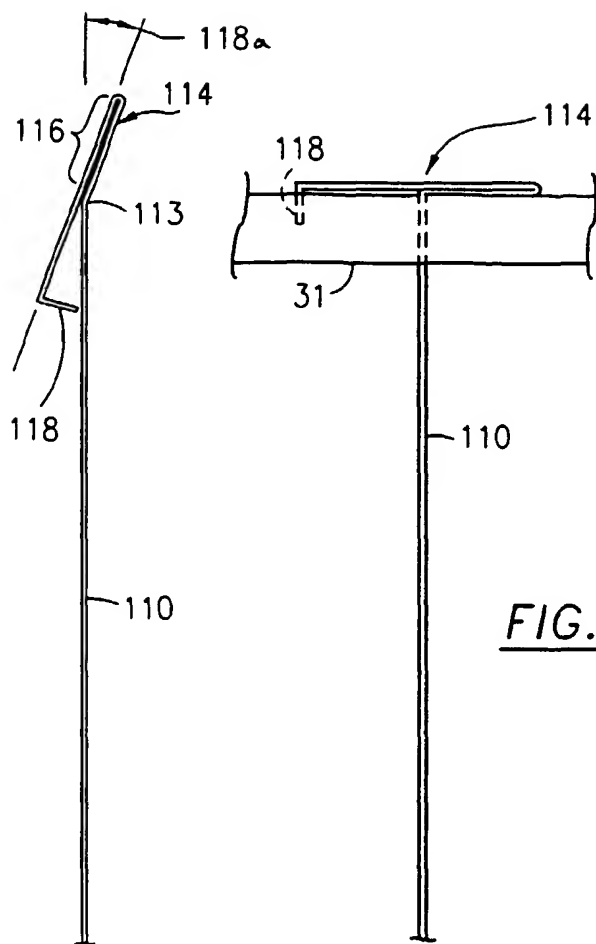


FIG. 21A

FIG. 21B

FIG. 21C

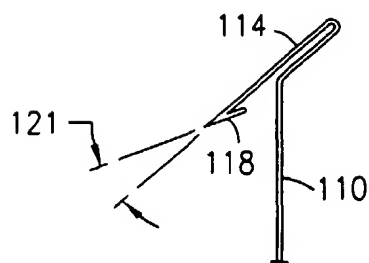
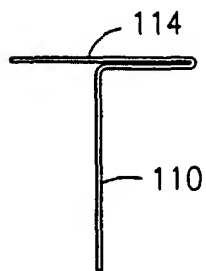
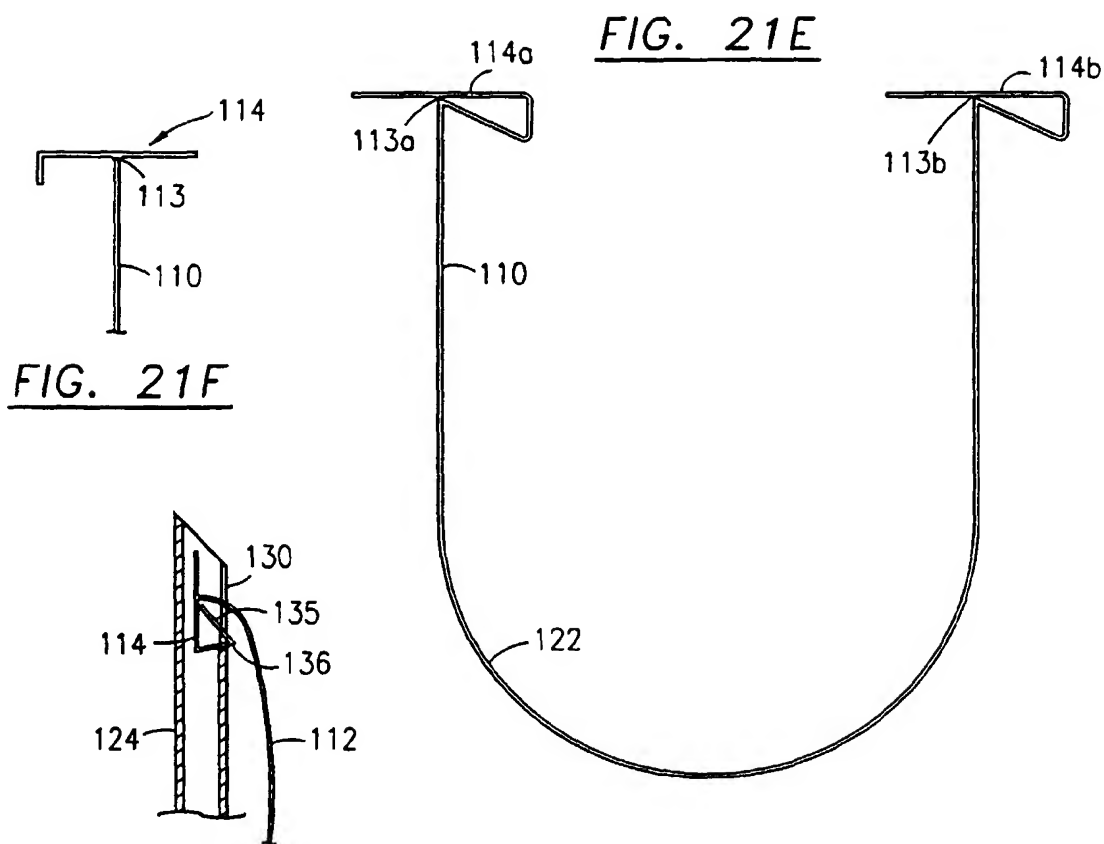


FIG. 21D



**FIG. 22A**

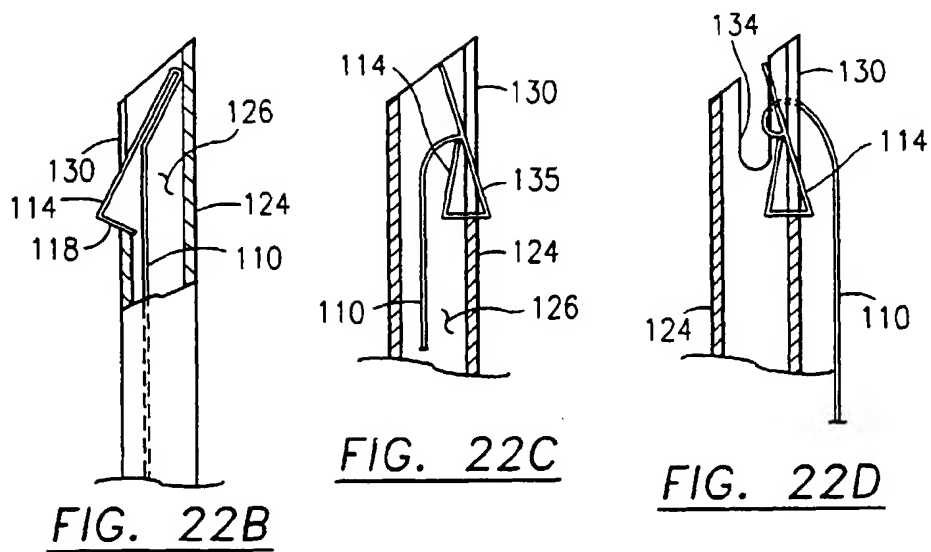


FIG. 23A

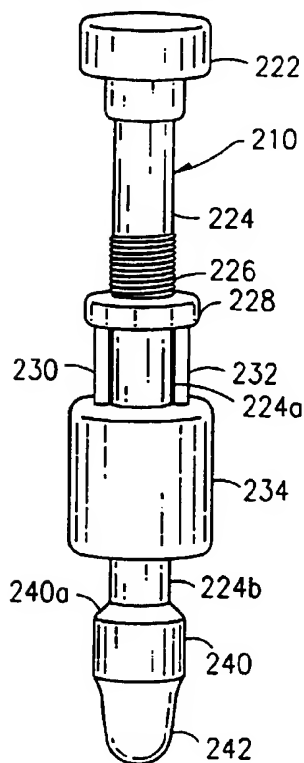


FIG. 23C

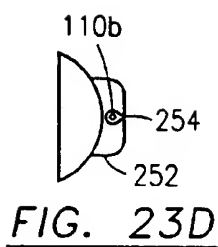
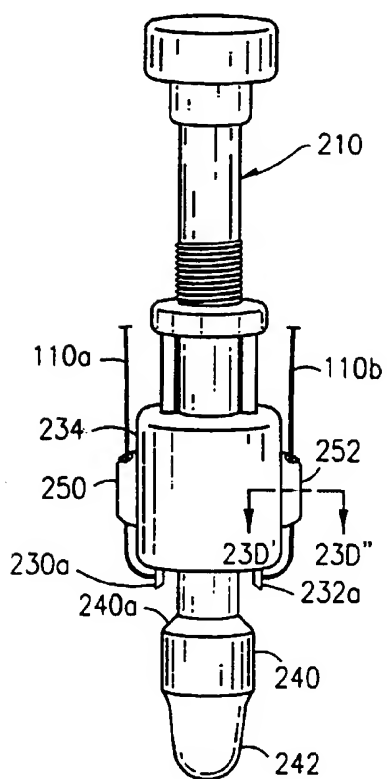


FIG. 23D

FIG. 23B

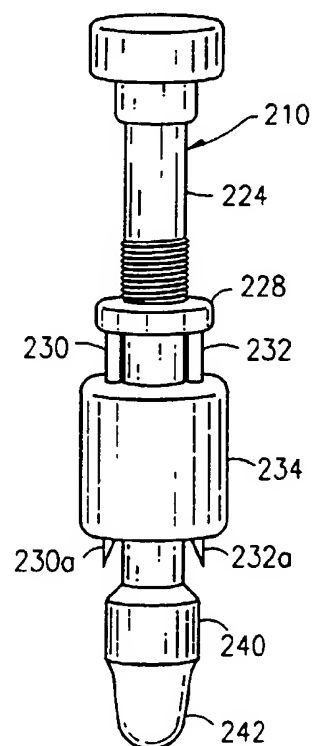


FIG. 24B

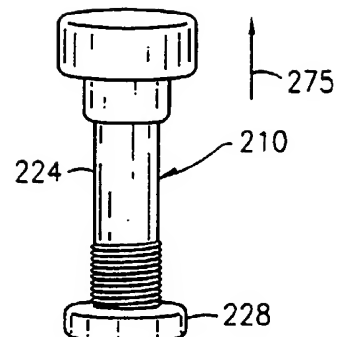


FIG. 24A

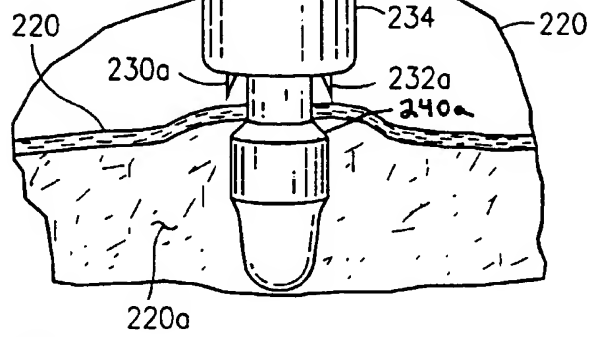
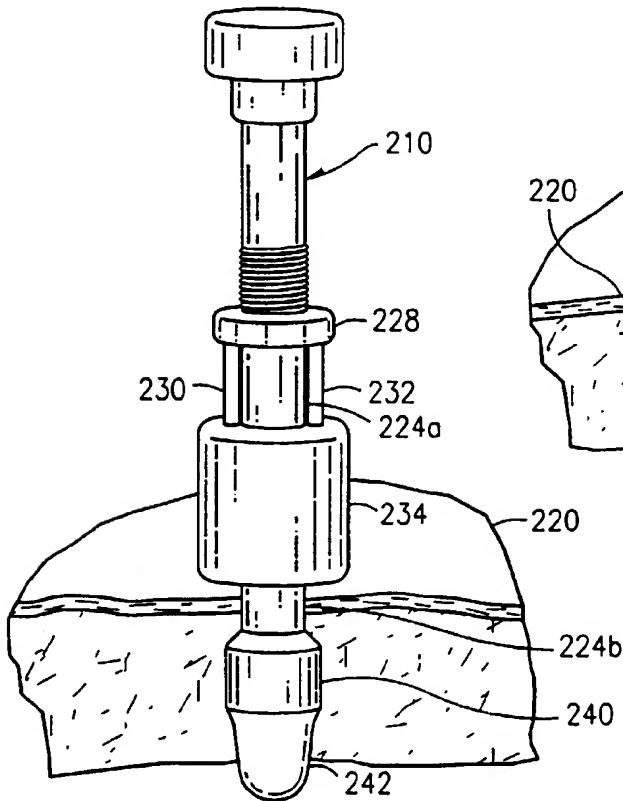


FIG. 24C

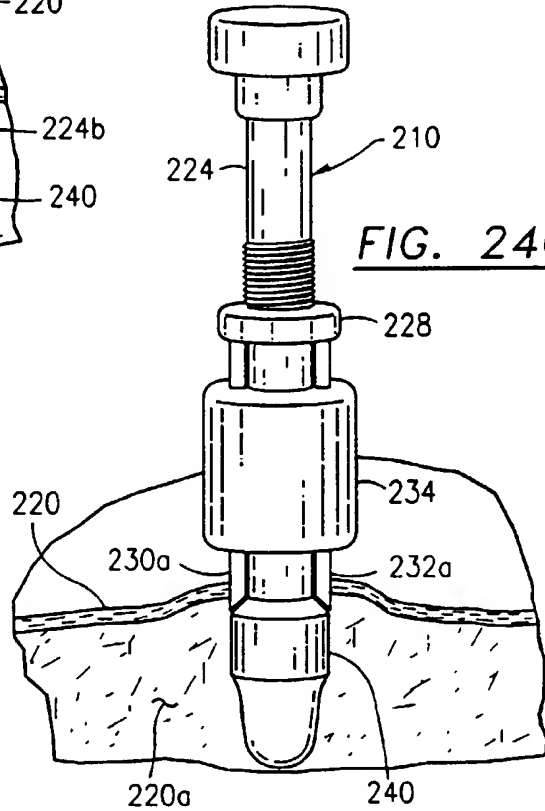




FIG. 25A

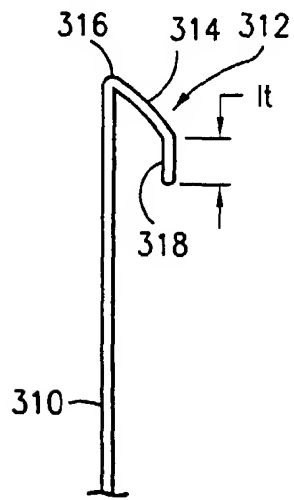


FIG. 25B

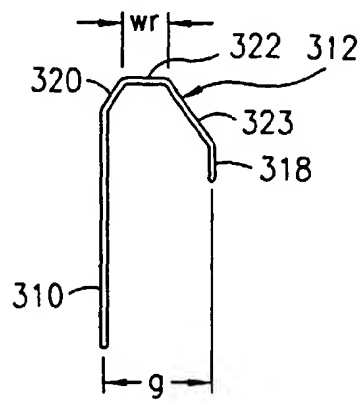


FIG. 25C

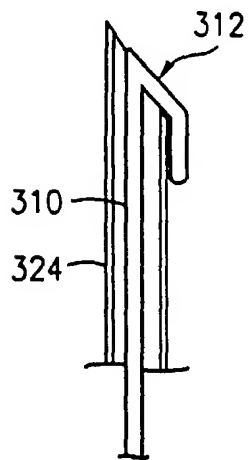


FIG. 25D

